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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,609	08/28/2003	Nabil El-Tayar	EL-TAYAR3B	5287

1444 7590 05/11/2007

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,609	EL-TAYAR ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 23-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-25* is/are allowed.

6)☒ Claim(s) *1-4 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response Applicants response filed 3/1/2007. Claims 23-28 have been added. Claims 1 and 4 have been amended. Claims 5-22 have been cancelled. Thus, claims 1-4 and 23-28 are pending and under consideration in this action.

2. Applicant has amend the title to better reflect the invention.

3. Applicant has amended the specification to update the priority information.

Claim Rejections - 35 USC § 112, first paragraph, maintained

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. The rejection of claims 1-4 and newly added claims 26-28 under 35 U.S.C 112, first paragraph, as lacking enablement is maintained for reasons set forth in the Office Action dated 10/18/06 (pages 3-6). Applicant's arguments have been fully considered but are not found to be persuasive. Applicant is asserting that the specification provides enabling disclosure for the method of treating infections, tumors and autoimmune and inflammatory diseases that are treatable with human fibroblast interferon (interferon- β). That is Applicant is asserting that the diseases and conditions described above are treatable with human fibroblast interferon (interferon-β). Applicant is claiming that support for this assertion is found at page 11, lines 27-31 of the specification. Contrary to Applicant's assertion page 11, lines 27-31 teaches that

"The PEG-polypeptide conjugate produced by the above method for stepwise attachment of two or more PEG moieties can be used to produce a medicament or pharmaceutical composition for treating diseases or disorders for which the polypeptides is effective as an active ingredient."

Thus, there is no disclosure of the various infections, tumors and autoimmune and inflammatory diseases that are treatable by the administering a polyol-interferon-β conjugate. Specifically, there is no support in the specification and prior art to indicate that the various disorders and diseases contemplated by the instant invention are treatable by interferon-β (Johnson et el, page 74; Platz et al. U.S. Patent No. 6, 479, 049, column 5).

With respect to claims 26-28, which written in Jepson format Applicant asserts that if a particular disorder or disease is treatable with human fibroblast interferon, then that disorder or disease is also treatable with an improvement to human fibroblast interferon where the human fibroblast interferon is in the form of a polyol-human fibroblast interferon conjugate. However, as argued above and indicated in the Office Action dated 10/18/06 (pages 3-6), there is no enabling support for treating all infections, tumors and autoimmune and inflammatory diseases broadly claimed in the instant invention. The prior art has disclosed treatment of viral infections including hepatitis B and C, basal cell carcinoma, brain tumor, skin cancer and multiple sclerosis (immune related disease) by administering interferon-β (Johnson et el, page 74; Platz et al. U.S. Patent No. 6, 479, 049, column 5). Since, there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation to try to formulate a treatment for various diseases with unrelated etiologies. In addition, because there are no working

examples provided describing diseases or models or modes of action for interferon-β, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention in its full scope. Since applicant has not provided any working examples to teach the method of treatment of a subject suffering from infections, tumors and autoimmune and inflammatory diseases by administering an effective amount of polyol-interferon-β conjugate either *in vitro* or *in vivo*, it would require an undue amount of experimentation to one of skill in the art to practice the invention commensurate in scope with the claims to treat all diseases disclosed.

Given the breadth of claims 26-28 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for a method of treatment of a subject suffering from infections, tumors and autoimmune and inflammatory diseases by administering an effective amount of polyol-interferon-β conjugate. Therefore, claims 1-4 and 26-28 (new added) remain rejected under 35 U.S.C 112, first paragraph, as lacking enablement.

4b. The rejection of claim 4 under 35 U.S.C 112, first paragraph, as written description is maintained for reasons set forth in the Office Action dated 10/18/06 (pages 6-8). Applicant is arguing that the amendment to the claims has obviated the rejection of record. Applicant' s argument has been fully considered but is not found to be persuasive because the claim was rejected for the recitation of "native human

interferon-β" which was found to be lacking written description support. Applicant has not amended the claim language ("native") nor addressed the language in the response. Therefore, claim 4 remains rejected under 35 U.S.C 112, first paragraph, as lacking written description support. Applicant amending the claim to recite only "human interferon-β" can obviate the rejection.

Claim Rejections - 35 USC § 112, second paragraph, maintained

5.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5a. The rejection of claim 4 under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter is maintained for reasons set forth in the Office Action dated 10/18/06 (page 8). Applicant is arguing that the amendment to the claims has obviated the rejection of record. Applicant' s argument has been fully considered but is not found to be persuasive because the claim was rejected for the recitation of "native human interferon-β" which was found to be vague and indefinite because not all native human interferon-β species have been identified. Applicant has not amended the claim language nor addressed the language in the response. Therefore, rejection of record is maintained. Applicant amending the claim to recite only "human interferon-β" can obviate the rejection.

6. Claims 23-25 are allowed. Claims 1-4 and 26-28 are rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647
May 4th, 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J Saoud